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December 13, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers lane, Room 1061
Rockville, MD 20852

RE: FDA Proposal to Regulate
Allograft Tissue
(Docket No. 97N-484)

Dear Sirs:

It has come to my attention that the Food and Drug Administration is proposing the regulation of allograft tissue as a medical device. As you may be familiar, allograft bone tissue is used extensively in orthopedic practice regardless of the sub-specialization. Allograft tissue has afforded us the opportunity to incorporate reconstructive options that do not and cannot be addressed with nonbiologic materials. The latter have significant, unique complications, which appropriately warrant a limited spectrum of application and appropriate regulation as medical devices.

To impose the same restrictions on allogenic tissue and to consider it as a medical device would severely compromise the ability to use this material by orthopedic surgeons. The opportunity to fashion this biologic material at the time of surgery allowing more appropriate approximation to the anatomical site being reconstructed is an inherent advantage of this material over metallic devices.

We are, therefore, of the opinion that regulation of allogenic bone and soft tissue would compromise reconstructive options now afforded thousands of people a year in this country. Mandating this biologic tissue a medical device would impose logistic difficulties making it much more difficult to be considered as a viable therapeutic option.

We would strongly ask you to reconsider your position and feel that additional regulation of allogenic tissue should not be promulgated at this time.

Yours sincerely,

M. G. Rock, M.D.
Director,
Mayo Clinic Bone Bank

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Chair,
Department of Orthopedic Surgery

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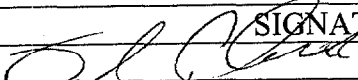
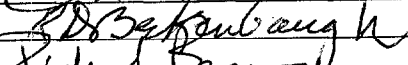
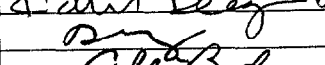


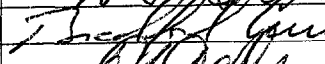
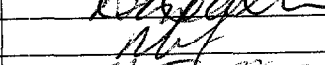
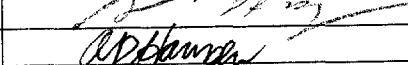
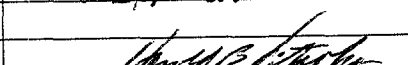
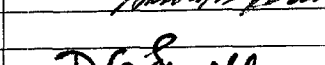


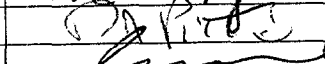


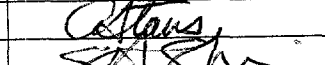
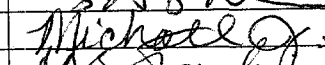

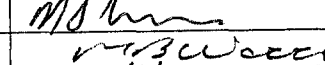
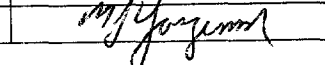
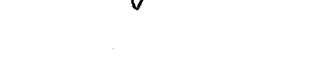





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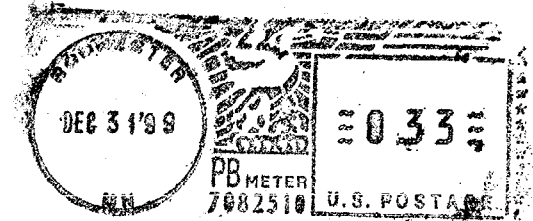
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